

 <p>agriculture, forestry & fisheries</p> <p>Department: Agriculture, forestry & fisheries REPUBLIC OF SOUTH AFRICA</p>	<p style="text-align: center;">CONFIDENTIAL</p> <p style="text-align: center;">APPLICATION FORM FOR THE REGISTRATION OF FEED ADDITIVES FERTILISERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947</p> <p style="text-align: center;">Registrar Act 36 of 1947 Agriculture Building, Beatrix Street, Pretoria Private Bag X343, Pretoria, 0001</p>
--	--

Instructions: This application form must be completed in duplicate. It must only be signed by the applicant, employee of the applicant in case of a business or a person who has been given power of attorney by the applicant to sign on his/her and such proof must accompany this application. Only South African residents or employees of a business that has a South African office and address can complete this application form. This application form can be used to register more than one feed additive provided that the feed additive is the same and only differs in the trade name or efficacy

APPLICANTS DETAILS	
<i>Particulars to be supplied</i>	<i>Complete this side</i>
Applicants name Company registration number Identity number (if its an Individual)	
<i>Contact details</i> Postal address Postal code Street/Physical address Telephone number Fax number E-mail address	
APPLICANT CATEGORY	<i>Tick relevant category</i>
1. Importer for own use	
2. Importer to sell/retail	
3. Importer for own use and to sell/retail	
4. Manufacturer for own use	
5. Manufacturer to sell/retail	
6. Manufacturer for own use and sell/retail	
7. Local trader/distributor/seller	



agriculture, forestry & fisheries

Department:
Agriculture, forestry & fisheries
REPUBLIC OF SOUTH AFRICA

CONFIDENTIAL

**APPLICATION FORM FOR THE REGISTRATION OF FEED
ADDITIVES
FERTILISERS, FARM FEEDS, AGRICULTURAL REMEDIES
AND STOCK REMEDIES ACT, 1947**
Registrar Act 36 of 1947
Agriculture Building, Beatrix Street, Pretoria
Private Bag X343, Pretoria, 0001

Instructions: If the manufacturer is outside the Republic of South Africa, proof of compliance by the manufacturer with local authorities/ legislation in the country of origin must be supplied.

MANUFACTURER DETAILS	
<i>If more than one manufacturer and/or manufacturing site supply this information by duplicating this page</i>	
Name	
Postal Address	
Street/Physical Address	
Telephone number	
Fax number	
E-mail address	
Country	
Facilities accreditation/ licensing (information)	
Sterilization installation registration (<i>if applicable</i>)	
<i>Details of Responsible Person</i>	
Name and surname	
Qualifications	
Professional registration	



agriculture, forestry & fisheries

Department:
Agriculture, forestry & fisheries
REPUBLIC OF SOUTH AFRICA

CONFIDENTIAL

APPLICATION FORM FOR THE REGISTRATION OF FEED ADDITIVES FERTILISERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947

Registrar Act 36 of 1947
Agriculture Building, Beatrix Street, Pretoria
Private Bag X343, Pretoria, 0001

(Note: Any person who in any application makes any statement which is false in any material respect, knowing it to be false, or fails to disclose any information with intent to deceive, shall be guilty of an offence).

DECLARATION

I hereby certify that the information furnished in this application is to the best of my knowledge true, correct, complete and complies with the requirements of Act No. 36 of 1947; acknowledge my responsibilities in terms of the Act; and grant permission to the Registrar of Act No.36/1947 to cancel this registration in terms of *Section 4* of the Act should it be established that the information supplied in this application and with this application is not true and does not comply with the requirements of the Act.

Initials and Surname.....Signature.....

Capacity.....Date.....

DECLARATION TO BE MADE IN THE PRESENCE OF A JUSTICE OF PEACE/COMMISSIONER OF OATHS VERKLARING WAT VOOR 'N VREDEREGTER/KOMMISSARIS VAN EDE AFGELÊ MOET WORD

INITIALS AND SURNAME / VOORLETTERS EN VAN

.....
**SIGNATURE OF APPLICANT
HANDTEKENING VAN AANSOEKER**

.....
DATE/DATUM

.....
TEL. NO.

I certify that the deponent has acknowledged that he/she knows and understands the contents of this declaration which was sworn to/affirmed before me and the deponents signature/thumb print/mark was placed thereon in my presence.

Ek sertifiseer dat die verklaarder erken dat hy/sy vertrouwd is met die inhoud van die verklaring en dit begryp. Hierdie verklaring is beëdig/bevestig voor my en verklaarder se handtekening / duimafdruk / merk is in my teenwoordigheid daarop aangebring.

.....
**JUSTICE OF THE PEACE/VREDEREGTER
COMMISSIONER OF OATHS / KOMMISSARIS VAN EDE**



**agriculture,
forestry & fisheries**

Department:
Agriculture, forestry & fisheries
REPUBLIC OF SOUTH AFRICA

CONFIDENTIAL

**APPLICATION FORM FOR THE REGISTRATION OF FEED
ADDITIVES
FERTILISERS, FARM FEEDS, AGRICULTURAL REMEDIES
AND STOCK REMEDIES ACT, 1947**
Registrar Act 36 of 1947
Agriculture Building, Beatrix Street, Pretoria
Private Bag X343, Pretoria, 0001

First names and surname:
(BLOCK LETTERS / DRUKSKRIF)
Voornamen en van:

Designation (rank): *Ex Officio* Republic of South Africa
Amp (rang): Afrika Republiek van Suid-Afrika

Business address:
Besigheidsadres:
.....
(Street address must be stated / Straatadres moet ingevul word)

Date/Datum..... Place/Plek.....

<u>FOR OFFICE USE ONLY</u>	
The Registrar (Act 36 of 1947)	
The registration is Recommended..... * Not Recommended.....	
Technical Adviser	Date.....
* Any reason for not recommending an application for registration or any conditions that should be imposed on the registration must be attached in the form of a minute.	

TECHNICAL ADVISER'S COMMENTS:

.....
.....
.....
.....

TECHNICAL ADVISER

DATE

 <p>agriculture, forestry & fisheries</p> <p>Department: Agriculture, forestry & fisheries REPUBLIC OF SOUTH AFRICA</p>	<p style="text-align: center;">CONFIDENTIAL</p> <p style="text-align: center;">APPLICATION FORM FOR THE REGISTRATION OF FEED ADDITIVES</p> <p style="text-align: center;">FERTILISERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947</p> <p style="text-align: center;">Registrar Act 36 of 1947 Agriculture Building, Beatrix Street, Pretoria Private Bag X343, Pretoria, 0001</p>
--	--

ANNEXURE I

GENERAL DATA REQUIRMENTS FOR ADDITIVES (supply relevant additive information)

PART 1: APPLICATION OVER VIEW

- 1.1 Product rational
- 1.2 Active substance/ substances

PART 2: CHEMISTRY AND MANUFACTURE

- 2.1 IDENTITY OF ADDITIVE
 - 2.1.1 Proposed propriety name(s)
 - 2.1.2 Type of additive according to its main function
 - 2.1.3 Qualitative and quantitative composition (active substance, other components, impurities)
 - 2.1.4 Physical state, particle size
 - 2.1.5 Manufacturing process including any specific processing process
- 2.2 SPECIFICATIONS CONCERNING ACTIVE SUBSTANCE
 - 2.2.1 Name according to main active as described by IUB/IUPAC, EINECS and CAS Number
 - 2.2.2 The biological origin, the activities towards relevant chemically pure model substrates and other physico-chemical characteristics
 - 2.2.3 Purity (checking the level of contaminating microorganisms, heavy metals, absence of toxins relevant to the source organism as shown by suitable method, absence of antibiotic activity at feed concentration level as determined by a suitable method, and composition of the non-active components (i.e. Total Organic Solids)
 - 2.2.4 Optimal pH, purification process and media used
- 2.3 PHYSIO-CHEMICAL, TECHNOLOGICAL AND BIOLOGICAL PROPERTIES OF THE ADDITIVE
 - 2.3.1 Stability on exposure to environmental conditions such as light, temperature, pH, moisture, and oxygen. Expiry date
 - 2.3.2 Stability during the preparation of premixtures and feedingstuff, in particular stability to heat, pressure and moisture. Possible decomposition product
 - 2.3.3 Stability during the storage of premixtures under defined conditions (Storage time under defined condition) Shelf life
 - 2.3.4 Other appropriate physico-chemical, technological or biological properties such as stability to obtain homogenous mixtures in premixtures and feedingstuffs, dust-forming properties, assessment of resistance to degradation or loss of biological activity in the digestive tract or by system of stimulation in vitro
 - 2.3.5 Physico-chemical or biological incompatibilities or interactions (e.g. with feedingstuffs, other approved additives or medicinal products)
- 2.4 CONTROL METHODS
 - 2.4.1 Description of the methods used for the determination of the criteria listed under items 2.1.3, 2.2.3, 2.2.4, 2.2.5, 2.3.2, 2.3.3 and 2.3.4
 - 2.4.2 Description of the qualitative and quantitative analytical methods for routine control of the additive in premixtures and feedingstuffs



agriculture, forestry & fisheries

Department:
Agriculture, forestry & fisheries
REPUBLIC OF SOUTH AFRICA

CONFIDENTIAL

**APPLICATION FORM FOR THE REGISTRATION OF FEED
ADDITIVES
FERTILISERS, FARM FEEDS, AGRICULTURAL REMEDIES
AND STOCK REMEDIES ACT, 1947**
Registrar Act 36 of 1947
Agriculture Building, Beatrix Street, Pretoria
Private Bag X343, Pretoria, 0001

PART 3 TOXICOLOGY

- 3.1 STUDIES ON LABORATORY ANIMALS (WHEN THE ACTIVE SUBSTANCE IS AS NON-PHOTOGENIC MICRO-ORGANISM FOUND NATURALLY THESE TYPES OF STUDIES MAY NOT BE NECESSARY)
- 3.2 ACUTE TOXICITY
 - 3.2.1 Acute inhalation toxicity
 - 3.2.2 Skin and eye irritancy
- 3.3 MUTAGENICITY
 - 3.3.1 Ames/Salmonella test
 - 3.3.2 Chromosomal aberration test
- 3.4 PHARMACOKINETICS ASPECTS
- 3.5 SUBCHRONIC TOXICITY
- 3.6 CHRONIC TOXICITY/CARCINOGENICITY
- 3.7 REPRODUCTIVE TOXICITY

PART 4 METABOLISM AND TOXICOKINETICS

PART 5 RESIDUES

PART 6 REGULATORY STATUS IN OTHER COUNTRIES

PART 7 OCCUPATIONAL HEALTH AND SAFETY

PART 8 ENVIRONMENTAL STUDIES

PART 9 EFFICACY AND SAFETY

- 9.1 STUDIES CONCERNING THE EFFICACY OF THE ADDITIVE
 - 9.1.1 Broiler trails
 - 9.1.2 Layer hen trails
 - 9.1.3 Turkey trails
 - 9.1.4 Piglet trials
 - 9.1.5 Fattening pig trials
 - 9.1.6 Sow trails
 - 9.1.7 Ruminant trials
 - 9.1.8 Other relevant trials
- 9.2 STUDIES CONCERNING THE SAFETY OF THE TARGET ANIMAL
 - 9.2.1 Chicken for fattening
 - 9.2.2 Laying hens
 - 9.2.3 Turkey for fattening
 - 9.2.4 Piglets
 - 9.2.5 Sows
 - 9.2.5 Ruminant trials
 - 9.2.6 Other relevant trials

PART 10 OTHER TRADE ASPECTS

- 10.1 STUDIES CONCERNING THE QUALITY OF THE ANIMAL PRODUCE
- LIST OF ENCLOSURES

REFERENCES